

Subject: RE: statement from UC San Diego
From: "Carr, Jacqueline" <jcarr@ucsd.edu>
Date: 4/11/19, 7:43 AM
To: Brad Racino <bradracino@inewssource.org>
CC: "Lafee, Scott" <slafee@ucsd.edu>

Hi Brad- Here you go:

1. As answered, Dr. Zhang's suspension as a PI on protocols is ongoing. The findings were limited to human subjects research.
2. Extensive communications were conducted with FDA, including a summary of the restrictions on Dr. Zhang's human subjects research. Dr. Zhang informed the IRB that he made CIRM aware of the protocol violations for CIRM sponsored research and he indicated that CIRM provided a response to his notification.
3. The findings from the AMAS audit were limited to UCSD research.
4. The AMAS report included studies that were no longer active.

Jacqueline Carr
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UC San Diego Health Sciences
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From: Brad Racino [bradracino@inewssource.org]
Sent: Wednesday, April 10, 2019 11:40 AM
To: Carr, Jacqueline
Cc: Lafee, Scott
Subject: Re: statement from UC San Diego

Thank you Jackie. I'm hoping you can answer some follow-up questions as soon as possible.

1. How long was Dr. Zhang's suspension? Or is it still ongoing? And why only clinical trials opposed to any research involving human subjects?
2. Did UCSD alert any oversight agencies, such as the NIH, FDA, OHRP, ORI, or California Medical Board to its audit findings?
3. In the same vein, did UCSD alert any institutions where Zhang conducts research, including the San Diego VA?
4. The audit examined Zhang's current research. Did UCSD look at any other previous research he had done? If not, please explain the reasoning, considering its finding violations in 100 percent of the studies that involved enrolled human subjects.

I appreciate the help.

-Brad

Carr, Jacqueline

April 10, 2019 at 10:57 AM

Hi Brad- Thank you for your patience in waiting for a response. Here is the statement from UC San Diego related to Dr. Kang Zhang:

MEDIA STATEMENT

As a result of the 2017 FDA warning letter and subsequent UCSD Ophthalmology Human Subjects Research Compliance report you referenced, UC San Diego implemented a comprehensive management action plan to address these issues, including document corrections, retraining key personnel, requiring a secondary screening process, and suspending Dr. Kang Zhang from serving as principal investigator (PI) on any protocols.

Best, Jackie

Jacqueline Carr

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Good afternoon Jackie,

In the course of researching the human research study done at the San Diego VA, we came across [a UC audit](#) and [FDA warning letter](#) specific to Dr. Kang Zhang, who is the Chief of Ophthalmic Genetics and a Professor of Ophthalmology at UCSD.

The audit and warning letter found a number of problems with several of Zhang's studies. We have passed the findings along to several experts for their review, and so far all have said the major findings are troubling and appear to show a pattern.

We would like to interview Dr. Zhang and/or Robert Weinreb – the chair of the Shiley Eye Institute where Dr. Zhang works – about the audit and letter, any corrective actions taken and steps to ensure future compliance.

Please let me know if you can help arrange that interview, and/or provide any additional context, findings, reviews or relevant documents related to Dr. Zhang's research.

Thank you for your help.

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